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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,296

06/28/2004

Yuji Yamazaki

081356-0218

7715

22428 7590 01/30/2007
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

SKELDING, ZACHARY S

ART UNIT

PAPER NUMBER

1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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DETAILED ACTION

1. Applicant's election, filed November 10, 2006, is acknowledged.

Claims 1, 2, 4, 6, 8 and 10-25 are pending.

2. **Applicant's election, of species "anti-FGF-23 antibodies that bind amino acid 25-179 of SEQ ID NO:1"**, in the reply filed on November 10, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, the restriction requirement is maintained and made **FINAL**.

Accordingly, claims 20-25 are under examination as they read on "anti-FGF-23 antibodies that bind amino acid 25-179 of SEQ ID NO:1".

Moreover, claims 1, 2, 4, 6, 8 and 10-19 have been withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being directed to a non-elected Groups/Species.

3. The Information Disclosure Statement filed January 13, 2006 has been considered by the examiner.
4. The rejections of record can be found in the previous Office Action, mailed January 13, 2006.

This Office Action is in response to applicant's amendment submitted July 12, 2006 and applicant's election of species submitted filed November 10, 2006.

All prior objections and rejections not mentioned below have been withdrawn.

5. The instant application is a national stage entry of PCT/JP03/00017 filed January 6, 2003.

Thus, according to 35 U.S.C. § 119(a), the instant application is entitled to claim the benefit of priority of a foreign application filed ≤ 1 year before the filing date of PCT/JP03/00017, i.e., on or after January 6, 2002.

Therefore, the instant application is entitled to claim the benefit of priority for JP 2002-262020, filed September 6, 2002 but not for 2001-401689, filed December 28, 2001.

With respect to the instant claims under examination, it is noted that JP 2002-262020 appears to provide sufficient supported under 35 U.S.C. § 112, 1st paragraph. ***Therefore the instant claims are given the effective priority date of September 6, 2002.***

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Moreover, it is further noted for the record that JP 2002-262020 discloses the "2C3B" anti-FGF-23 antibody, its deposit identifiers "FERM BP-7838" and that it is an FGF-23 neutralizing antibody. However, while JP 2002-262020 discloses the "2C5L" antibody and discloses that it was deposited, JP 2002-262020 does *not* appear to disclose the "2C5L" deposit identifier or that the "2C5L" antibody is a neutralizing antibody which does not compete with "2C3B" antibody for binding to FGF-23.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Claims 22 and 25 rejected under 35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a pharmaceutical composition of an antibody produced by FERM BP-7838 or FERM BP-8268, or an antibody which competes with said antibodies, which is effective against X-linked hypophosphatemic rickets, hypophosphatemia, osteoporosis and the particular complications of decreased renal function and hemodialysis, "renal osteodystrophy or dialysis osteopathy", *does not reasonably provide enablement for* an antibody produced by FERM BP-7838 or FERM BP-8268, or an antibody which competes with said antibodies, *which is effective against "renal failure"*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

More particularly, according to the instant specification, renal failure causes high levels of serum phosphate, and apparently in response, as FGF-23 is a phosphatonin, animals produce high levels of FGF-23 to clear the high levels of serum phosphate. Furthermore, according to the instant specification, the high levels of FGF-23 induces "some complications in decreased renal functions and in hemodialysis patients," such as "diseases involving abnormalities in bone metabolism accompanying decreased renal functions, such as renal osteodystrophy, and dialysis osteopathy". (see instant specification, page 21 and Example 25, pages 92-93).

Thus, high levels of FGF-23 are a symptom of renal failure, not a cause.

Therefore, the skilled artisan would be unable to make an FGF-23 antibody which is effective to treat "renal failure", per se, as treating "renal failure" would specifically require treating the defective kidney, per se, and there is insufficient direction or guidance in the instant specification that FGF-23 is capable of doing so.

Accordingly, undue experimentation would be required to produce the claimed invention commensurate with the scope of the claims from the written disclosure alone. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In

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view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Thus, the instant claims are not enabled.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 23-25 are rejected under 35 U.S.C. § 102(b)** as anticipated by Itoh et al. (WO 01/66596, cited on applicant's IDS of June 28, 2004), as evidenced by Yu et al. (Endocrinology. 2005 Nov;146(11):4647-56) and Mohammadi et al. (Cytokine Growth Factor Rev. 2005 Apr;16(2):107-37)(See entire documents).

As a preliminary matter, it is noted that the species of antibodies under examination (2C3B, aka "BP-7838" and 2C5L, aka "BP-8268") bind somewhere within amino acids 25-179 of SEQ ID NO: 1, and SEQ ID NO: 1 is identical to human FGF-23 (see, in particular Figure 5 and Example 36, pages 113-114 of the instant specification).

Itoh teaches human FGF-23 encoded by SEQ ID NO:4 which is 100% identical to SEQ ID NO:1 of the instant application (see attached alignment). Itoh further teaches that upon expression, FGF-23 is proteolytically cleaved into two fragments, a large N-terminal fragment extending from amino acid 1 to around amino acid 179 and a smaller C terminal remainder extending from around amino acid 180 to C-terminal residue 251.

Itoh further teaches that antibodies can be generated against either FGF-23 proteolytic fragment, and that said antibodies can be used for "preventing or treating diseases involving overexpression of the FGF-23 protein," such as "X-linked Hypophosphatemic rickets" (see Itoh page 18, 3rd to 4th paragraphs, page 30, 4th to 5th paragraphs and page 31, 2nd paragraph).

Yu teaches that FGF-23 binds to FGF receptors 1c, 2c, 3c and 4 (see entire document, in particular Discussion pages 4652-4655).

Mohammadi teaches that FGF polypeptides, including FGF-23, binds to FGF receptors via a conserved set of residues that are found within amino acids 1 to 179 of FGF-23, and these residues are primarily found along one face of the FGF conserved β -trefoil core (see, part 1-2, pages 107-120, in particular Figures 1 and 5).

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Given that the antibodies of Itoh bind the same sequence as the antibodies of the instant claims, i.e., amino acid 1-180 of FGF-23, and given that the antibodies of Itoh, like the instantly claimed antibodies, can be used to treat hypophosphatemic diseases involving overexpression of FGF-23, such as X-linked Hypophosphatemic rickets, and further given the highly conserved receptor binding surface of the FGF molecules, including FGF-23, as evidenced by Wu and Mohammadi, the antibodies of Itoh would inherently compete with the instantly claimed antibodies.

Thus, the instant claims are anticipated by Itoh as evidenced by Yu and Mohammadi.

Since the Office does not have a laboratory to test the reference antibodies and determine if they compete with the instantly claimed antibodies, it is applicant's burden to show that the reference antibodies are not competitive with the instantly claimed antibodies. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

10. **Claims 23-25 are rejected under 35 U.S.C. § 102(a)** as anticipated by Yamashita et al. (WO 02/14504, cited herewith), as evidenced by Yamashita et al. (US 2004/0082506, cited on the Examiner's 892 of January 13, 2006), Yu et al. (Endocrinology. 2005 Nov;146(11):4647-56), Mohammadi et al. (Cytokine Growth Factor Rev. 2005 Apr;16(2):107-37), and Bost et al. (Immunol. Invest. 1988; 17:577-586) (See entire documents).

As a preliminary matter, it is noted that the species of antibodies under examination (2C3B, aka "BP-7838" and 2C5L, aka "BP-8268") bind somewhere within amino acids 25-179 of SEQ ID NO: 1, and SEQ ID NO: 1 is identical to human FGF-23 (see, in particular Figure 5 and Example 36, pages 113-114 of the instant specification).

It is further noted that Yamashita et al., US 2004/0082506, is a 371 of Yamashita et al., WO 02/14504, published February 21, 2002 in the Japanese language. Therefore, Yamashita '506 is an English language copy of Yamashita '504. Accordingly, for the purposes of examination under 35 U.S.C. § 102(a), the following rejection will make reference to passages from US 2004/0082506, however the date being relied upon for the purposes of anticipation is the publication date of **Yamashita '504, February 21, 2002**.

Yamashita '506 teaches a protein encoded by SEQ ID NO:2 designated "OST-311" which is 100% identical to SEQ ID NO:1 of the instant application (see attached alignment). Yamashita further teaches that upon expression, OST-311 is proteolytically cleaved into two fragments, a large N-terminal fragment extending amino acid 1 to amino acid 179 and a smaller C terminal remainder extending from amino acid 180 to C-terminal residue 251 (see, in particular page 9, paragraph [0119]-[0122]). Yamashita further teaches antibodies can be generated against OST-311 fragments, and that said antibodies can be used for preventing or

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treating diseases involving overexpression of the FGF-23 protein such as “X-linked Hypophosphatemic rickets” (see, in particular claims 5, 10, 14 and 15 as well as specification page 11, paragraph [0139] to page 14, paragraph [0153] and page 15, paragraph [0170]-[0173]).

Yu teaches that FGF-23 binds to FGF receptors 1c, 2c, 3c and 4 (see entire document, in particular Discussion pages 4652-4655).

Mohammadi teaches that FGF polypeptides, including FGF-23, binds to FGF receptors via a conserved set of residues that are found within amino acids 1 to 179 of FGF-23, and these residues are primarily found along one face of the FGF conserved β -trefoil core (see, part 1-2, pages 107-120, in particular Figures 1 and 5).

Bost teaches that antibodies can be specific for a given epitope and cross-reactive with multiple antigens. For example, Bost teaches antibodies which cross-react with IL-2 and HIV envelope protein, and establish that the binding to each protein is due to the presence of a homologous sequence in each protein of six amino acids, four of which are identical (see entire document, in particular the Abstract and Discussion, pages 577 and 583-585). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (see, in particular Results, pages 579-583).

Given that the antibodies of Yamashita bind nearly the same sequence as the antibodies of the instant claims, i.e., Yamashita teaches antibodies that bind amino acids 34-201 of FGF-23 and the antibodies of the instant claims bind amino acid 1-180 of FGF-23, as evidenced by Bost, the antibodies of Yamashita would inherently bind amino acids 1-180 of FGF-23.

Moreover, given that the antibodies of Yamashita, like the instantly claimed antibodies, can be used to treat hypophosphatemic diseases involving overexpression of FGF-23/OST-311, such as X-linked Hypophosphatemic rickets, and further given the highly conserved receptor binding surface of the FGF molecules, including FGF-23, as evidenced by Wu and Mohammadi, the antibodies of Yamashita would be inherently competitive with the instantly claimed antibodies.

Thus, the instant claims are anticipated by Yamashita as evidenced by Yu, Mohammadi and Bost.

Since the Office does not have a laboratory to test the reference antibodies and determine if they compete with the instantly claimed antibodies, it is applicant's burden to show that the reference antibodies are not competitive with the instantly claimed antibodies. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

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11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 12-15 of copending USSN 10/344,339, in view of Yu et al. (Endocrinology. 2005 Nov;146(11):4647-56), Mohammadi et al. (Cytokine Growth Factor Rev. 2005 Apr;16(2):107-37), Bost et al. (Immunol. Invest. 1988; 17:577-586) (See entire documents).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of USSN 10/344,339 recite an antibody that binds a polypeptide consisting of a partial sequence of the amino acid sequence of SEQ ID NO: 2, wherein said partial sequence contains amino acids 34-201 of SEQ ID NO: 2 and deletions thereof, and wherein said sequence has hypophosphatemia-inducing activity. The reference claims also recite pharmaceutical compositions of said antibody wherein the antibody is effective against osteoporosis (claim 15).

The reference claims do not recite that the antibody competes with BP-7838 or BP-8268.

It is noted that the antibodies of the instant claims (2C3B, aka “BP-7838” and 2C5L, aka “BP-8268”) bind somewhere within amino acids 25-179 of SEQ ID NO: 1, and SEQ ID NO: 1 is identical to human FGF-23 (see, in particular Figure 5 and Example 36, pages 113-114 of the instant specification).

Yu teaches that FGF-23 binds to FGF receptors 1c, 2c, 3c and 4 (see entire document, in particular Discussion pages 4652-4655).

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Mohammadi teaches that FGF polypeptides, including FGF-23, binds to FGF receptors via a conserved set of residues that are found within amino acids 1 to 179 of FGF-23, and these residues are primarily found along one face of the FGF conserved β -trefoil core (see, part 1-2, pages 107-120, in particular Figures 1 and 5).

Bost teaches that antibodies can be specific for a given epitope and cross-reactive with multiple antigens. For example, Bost teaches antibodies which cross-react with IL-2 and HIV envelope protein, and establish that the binding to each protein is due to the presence of a homologous sequence in each protein of six amino acids, four of which are identical (see entire document, in particular the Abstract and Discussion, pages 577 and 583-585). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (see, in particular Results, pages 579-583).

Given that the antibodies of the reference claims bind nearly the same sequence as the antibodies of the instant claims, i.e., the reference claims teach antibodies that bind amino acids 34-201 of FGF-23, and the antibodies of the instant claims bind amino acid 1-180 of FGF-23, as taught by Bost, the antibodies of the reference claims would necessarily bind amino acids 1-180 of FGF-23.

Moreover, given that the antibodies of the reference claims, like the instantly claimed antibodies, can be used to treat osteoporosis, and further given the highly conserved receptor binding surface of the FGF molecules, including FGF-23, as taught by Wu and Mohammadi, the antibodies of the reference claims would necessarily compete with the instantly claimed antibodies.

Thus, it would have been obvious to one of ordinary skill in the art that USSN 10/344,339 teaches the instant claims in light of the teaching of Yu, Mohammadi and Bost.

This is a provisional obviousness-type double patenting rejection.

13. Claims 23-25 directed to an invention not patentably distinct from claims 10 and 12-15 of commonly assigned USSN 10/344,339. Specifically, for the same reasons put forth above in the obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned USSN 10/344,339, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.


14. Claims 20 and 21 are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
January 22, 2007


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

4 page alignment
attached

(Z.S.) 1-22-07

4 page
Alignment
attached
to
10/30/2006

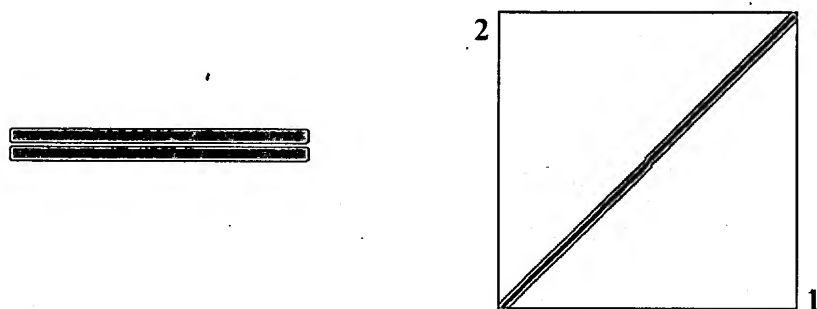
BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.15 [Oct-15-2006]

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 x_dropoff: expect: wordsize: Filter ☐ View option:
 Masking character option: Masking color option:
☐ Show CDS translation

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Sequence 2: lcl|Yamazaki_sin1
Length = 251 (1 .. 251)

(2.s.) 1-22-06



NOTE: Bitscore and expect value are calculated based on the size of the nr database.

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Gapped

Lambda	K	H
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Gap Penalties: Existence: 11, Extension: 1

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Number of extensions: 255

Number of successful extensions: 1

Number of sequences better than 10.0: 1

Number of HSP's gapped: 1

Number of HSP's successfully gapped: 1

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Length adjustment: 131

Effective length of query: 120

Effective length of database: 1,538,025,375

Effective search space: 184563045000

Effective search space used: 184563045000

Neighboring words threshold: 9

X1: 16 (7.4 bits)

X2: 129 (49.7 bits)

X3: 129 (49.7 bits)

S1: 41 (21.9 bits)

S2: 77 (34.3 bits)

BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.15 [Oct-15-2006]

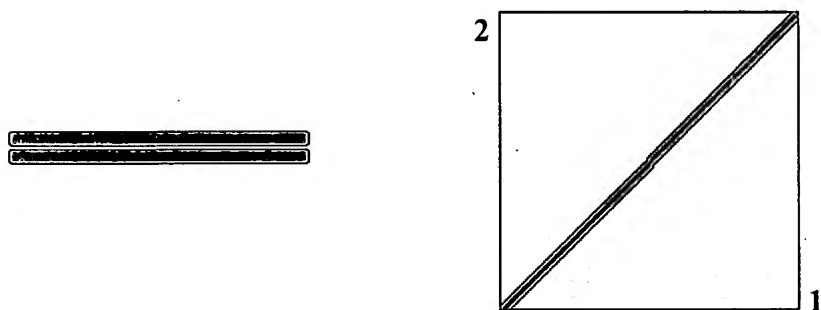
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Sequence 2: lcl|yamashita_sin2

Length = 251 (1 .. 251)



NOTE: Bitscore and expect value are calculated based on the size of the nr database.



Score = 528 bits (1360), Expect = 2e-148

Identities = 251/251 (100%), Positives = 251/251 (100%), Gaps = 0/251 (0%)

Query	1	MLGARLRLWVCALCSVCSMSVLRAYPNASPLLGSSWGGLIHLYTATARN	60
		MLGARLRLWVCALCSVCSMSVLRAYPNASPLLGSSWGGLIHLYTATARN	
Sbjct	1	MLGARLRLWVCALCSVCSMSVLRAYPNASPLLGSSWGGLIHLYTATARN	60
Query	61	VDGAPHQTIYSALMIRSEDAGFVVITGVMSRRYLCMDFRGNIFGSHYFDPENCRFQHQT	120
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Sbjct	61	VDGAPHQTIYSALMIRSEDAGFVVITGVMSRRYLCMDFRGNIFGSHYFDPENCRFQHQT	120
Query	121	ENGYDVYHSPQYHFLVSLGRAKRAFLPGMNPPPYSQLSRRNEIPLIHFNTPIPRRHTRS	180
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Sbjct	121	ENGYDVYHSPQYHFLVSLGRAKRAFLPGMNPPPYSQLSRRNEIPLIHFNTPIPRRHTRS	180
Query	181	AEDDSERDPLNVLKPRARMTAPASCSQELPSAEDNSPMASDPLGVVRGGRVNTHAGGTG	240
		AEDDSERDPLNVLKPRARMTAPASCSQELPSAEDNSPMASDPLGVVRGGRVNTHAGGTG	
Sbjct	181	AEDDSERDPLNVLKPRARMTAPASCSQELPSAEDNSPMASDPLGVVRGGRVNTHAGGTG	240
Query	241	PEGCRPFAKFI	251
		PEGCRPFAKFI	
Sbjct	241	PEGCRPFAKFI	251

CPU time: 0.02 user secs. 0.00 sys. secs 0.02 total secs.

Lambda	K	H
0.322	0.138	0.439

Gapped

Lambda	K	H
0.267	0.0410	0.140

Matrix: BLOSUM62

Gap Penalties: Existence: 11, Extension: 1

Number of Sequences: 1

Number of Hits to DB: 661

Number of extensions: 255

Number of successful extensions: 1

Number of sequences better than 10.0: 1

Number of HSP's gapped: 1

Number of HSP's successfully gapped: 1

Length of query: 251

Length of database: 1,538,025,506

Length adjustment: 131

Effective length of query: 120

Effective length of database: 1,538,025,375

Effective search space: 184563045000

Effective search space used: 184563045000

Neighboring words threshold: 9

X1: 16 (7.4 bits)

X2: 129 (49.7 bits)

X3: 129 (49.7 bits)

S1: 41 (21.9 bits)

S2: 77 (34.3 bits)